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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,671	09/24/2001	Antonio Parente Duena	P/ 189-162	4516

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EXAMINER
YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/22/2002 9

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/913,671	DUENA ET AL.	
	Examin r	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fuisz (USPN 5,518,730) in view of Yamamoto et al (USPN 4,954,298), Bodmer et al (USPN 5,538,739), and Canal et al (USPN 5,536,508). The claims recite a pharmaceutical composition comprising lacto-co-glycolic copolymer, a peptide and citric acid ethers. Fuisz teaches a pharmaceutical formulation comprising the copolymer, peptide and citric acid ethers of applicant (Abstract; col. 6, lin. 63 – 67; col. 8, lin. 40 – 42; col. 10, lin. 59 – 65; Table I). The remaining references teach the specific peptides claimed by applicant, and show the level of skill in the art. The references show that it is within the level of skill in the art to choose specific peptides to include in a pharmaceutical formulation. One of ordinary skill in the art would have been motivated to combine any of the encapsulated peptides of Yamamoto, Bodmer or Canal with the formulation of Fuisz in order to impart differing therapeutic or prophylactic properties on the formulation. The peptide of Yamamoto would impart luteinizing properties, while the peptides of Bodmer would impart properties to inhibit insulin release. It would have been obvious to one of ordinary skill in the art, at the time of the invention to combine these teachings with the

expected result of a sustain-release formulation useful in hormone therapy. The claims remain rejected as being obvious in view of the prior art.

Response to Arguments

4. Applicant's arguments filed 08/06/02 have been fully considered but they are not persuasive. Applicant argues that:

a. The pharmaceutical preparation of the invention consists of drug **nucleus**, which distinguishes it from the prior art.

b. The product of the Fuisz is **not** a polymer + drug + citric acid ester.

c. The supporting reference, Yamamoto, Bodmer and Canal do not teach the elements invention, specifically the use of citric acid esters.

5. Regarding argument a. and b., that the product of the invention and that of the reference differ due to the process by which they are made, it is the position of the examiner that these arguments are irrelevant since process limitations were not included in the originally filed claims. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a drug **nucleus**) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Further Fuisz teaches a product which reads on the product of the invention (Id.), irrespective of the process by which it is produced. On the other hand, when the process is taken in to consideration, applicant argues that a drug **nucleus** is produced, while Fuisz produces a homogeneous product. Though homogeneous in structure, the center of the product would

contain an amount of the active agent, with the surrounding constituents acting as layers. In this respect Fuisz again reads on this aspect of the claimed invention. As discussed in the original rejection Fuisz teaches a polymeric pharmaceutical preparation comprising a copolymer of lactic–co–glycolic acid, LHRH and citric acid esters, triethyl or tributyl citrate (Id.).

With regard to argument c., the supporting references being insufficient, it is the position of the examiner that this too is irrelevant. The references are used as support to show that is I s well known in the art to encapsulate varying peptides with PGLA copolymer. If the reference were complete with citric acid esters they would have served as 102 anticipation references, in stead they served to show the level of skill in the art. The references showed that following the suggestion of Fuisz (which included LHRH and in some embodiments human somatatropin) one of ordinary skill in the art would be able to substitute the peptides of the references into the formulation of Fuisz.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4: 30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MPY
October 19, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600